## Root Canal Irrigants and Medicaments in Endodontic Malpractice Cases: A Nationwide Longitudinal Observation

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## Abstract

Introduction: The aim of this study was to assess the role of root canal irrigants and medicaments in endodontic injuries verified in Finland and to estimate the rate of such events over time. Methods: The study material comprised all endodontic injuries verified by the Patient Insurance Centre in 2002 to 2006 (n = 521) and 2011 to 2013 (n = 449). The data, based on patient documents scrutinized by 2 specialists in endodontics, included patients' and dentists' sex and age and the service sector. We recorded the use of root canal irrigants and medicaments, each as a dichotomy. Furthermore, we dichotomized the injuries as those related to root canal irrigants/medicaments and any other injuries. The injuries were also dichotomized as avoidable (could have been avoided by following good clinical practice) or unavoidable (normal treatment-related risks). Statistical evaluation used chi-square tests and t tests; logistic regression produced odds ratios (ORs). Results: The verified injuries (N = 970) comprised 635 (65%) avoidable and 335 (35%) unavoidable injuries. The number of irrigant-/medicament-related injuries was 69, accounting for 7.1% of all verified injuries; all resulted from sodium hypochlorite and calcium hydroxide, and 87% were avoidable. The overall rate of sodium hypochlorite/calcium hydroxide injuries was 4.3 cases per 100,000 endodontic patients per year. Compared with other injuries, sodium hypochlorite/calcium hydroxide injuries were more likely avoidable (OR = 3.8) and more than 5-fold likely in 2011 to 2013 than in 2002 to 2006 (OR = 5.6). Conclusions: Extreme care is needed when applying sodium hypochlorite and calcium hydroxide into root canals to avoid increasing harmful consequences. (J Endod 2018; =:1-6)

### **Key Words**

Calcium hydroxide, endodontics, injury, root canal irrigant, root canal medicament, sodium hypochlorite Preparation of infected root canals requires plentiful rinsing to clean and disinfect the canal system. Because of its high antibacterial property, sodium hypochlorite (NaOCl) is the leading irrigant (1, 2). Interappointment

### Significance

We observed a marked increase in accidents related to the use of sodium hypochlorite and calcium hydroxide. Their application calls for extreme caution to avoid the harmful and potentially lifelong consequences of substance spreading into tissues outside the root canals.

medication is needed to prevent the growth of microbes between visits. To this end, calcium hydroxide  $(Ca(OH)_2)$  is commonly used. Both chemicals are strongly alkaline (pH = 12-14) and will cause harm when forced out of the root canals. Current guidelines for root canal treatment (3-6) stress the need for voluminous use of irrigating solution but also suggest avoiding its extrusion beyond the foramen. The same guidelines recommend Ca $(OH)_2$  as the intracanal medication during multiple treatments.

Techniques for getting a sufficient amount of irrigant to the root canal system include pipettes, syringe needles, and various machine-driven systems (7). In everyday practice, dentists have largely adapted new techniques either by lessons and self-learning of clinical series published in dental journals or under guidance given by commercial companies.

Several case reports and reviews have described harmful incidents after inadvertent contact of NaOCl or Ca(OH)<sub>2</sub> with soft tissues outside root canals (8–15). Although these incidents are relatively rare (16), their consequences are dramatic and may lead to lifelong suffering of the patient. Recently, some articles have given detailed instructions for the prevention or management of NaOCl accidents (3, 14, 17–19). Previous research on the harmful incidents related to NaOCl or Ca(OH)<sub>2</sub> consists solely of case reports, which allow no estimates of the rate of such events. Therefore, we evaluated a nationwide set of records on endodontic injuries verified in the 2000s in Finland to assess the role of root canal irrigants and medicaments in the injuries and estimate the rate of injuries at the population level.

## **Materials and Methods**

## Background

In Finland, the private and public sectors of oral health care services are almost equal in size. The public sector provides dental care to children (< 18 years) free of charge. Adults can use services from either sector, but the fees in the public sector are subsidized and notably smaller than those in the private sector, even after partial reimbursement for dental care from the Social Insurance Institute.

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## **Clinical Research**

Failures in health care in Finland and other Nordic countries are treated according to fairly similar systems that follow the "no blame/no fault" rule. Based on the Patient Injury Act of 1987 in Finland, all health care workers must have a patient insurance contract. The Patient Insurance Centre (PIC) handles patient health care claims and decides about the indemnity of a financial compensation for cases in which the injury could have been avoided by following good clinical practice. Patients who feel that their dental care has been substandard or has resulted in injury can submit a claim to PIC free of charge using forms available at service points and online. Submission of a claim has no restrictions regarding patient's age, service sector, or type of treatment.

Each claim is first registered in the PIC electronic database with the claimant's explanation of the incidence. After that, the PIC requests patient documents from the care provider, who is asked to give in his or her own words any additional details related to the incident. The PIC decisions are based on these documents. As part of this process, the PIC advisors assess each claim in detail and make a suggestion about whether or not there was an injury and in injury cases whether or not it had been avoidable (could have been avoided by following good clinical practice) or unavoidable (normal treatment-related risks). All PIC advisors are experienced clinicians, and they discuss the cases in monthly meetings to keep their suggestions standardized.

In 2011 to 2016, PIC handled an annual average of 7700 claims, 700 of which were related to dental care, but no detailed information about the types of injuries is given in the PIC official statistics. Previous research reports from Finland have shown that endodontics predominate in dental malpractice claims in the 2000s, reaching up to 200 claims annually (20, 21). A recent report from the United States describes a similar increasing trend in dental malpractice cases from 2004 to 2014 (22).

## **Ethical Considerations**

Our study is based on decisions made by the PIC on endodontic malpractice claims in 2002 to 2006 and 2011 to 2013. The PIC, together with the Ministry of Social Affairs and Health, approved the

study protocol. To further ensure fulfillment of ethics criteria, running numbers were the only identifiers for the cases in the database.

## **Data Collection**

The target cases covered all endodontic malpractice claims with decisions made by the PIC in 2002 to 2006 and 2011 to 2013. We selected the 2 periods to illustrate changes in the frequency and type of injuries over time. Two dental advisors, both specialists in endodontics, scrutinized all documents gathered of the endodontic malpractice claims. For the present study, the PIC advisors first recorded the document-based raw data on a computerized platform created for this purpose. Later, we tested the data for logicality and possible errors and corrected any mistakes to fit the recordings with original patient documents, rescrutinized by 1 of the authors (O.S.). After excluding 51 incomplete cases, a total of 1271 cases formed the target data basis for this study. According to the PIC decisions, 970 of the 1271 cases had a verified injury and, thus, were analyzed here.

## **Data on Injury Cases**

The data included the patients' sex and age; the service sector in which the treatment took place; and the dentists' sex, age, and specialization, if any. The teeth in question were categorized as anteriors (incisors and canines), premolars, or molars. Information gathered from the patient documents for this study included details about the use of root canal irrigants and medicaments, each recorded as a dichotomy and using their generic names.

The injuries recorded were perforation of the root canal or pulp chamber; a broken root canal instrument; injuries caused by any root canal irrigants and medicaments; and miscellaneous injuries such as under/overfilling, wrong diagnosis, and unnecessary treatment. For this study, we dichotomized the injuries as being or not being caused by root canal irrigants or medicaments. These statements were based on the providers' detailed information about the incidences and related symptoms and actions needed. As part of processing the claims, the PIC advisors categorized the type of injuries as avoidable or unavoidable.

TABLE 1. Characteristics of Cases with Endodontic Injuries Verified by the Patient Insurance Centre in Finland in 2002 to 2006 and 2011 to 2013

Characteristics of cases	All injuries, n (%)	Avoidable, <i>n</i> (%)	Unavoidable, <i>n</i> (%)	P value
Total (in 8 years)	970 (100)	635 (65.5)	335 (34.5)	_
Data periods (years)				
2002–2006	521 (100)	356 (68.3)	165 (31.7)	.043
2011–2013	449 (100)	279 (62.1)	170 (37.9)	
Patients				
Women	690 (100)	454 (65.8)	236 (34.2)	.732
Men	280 (100)	181 (64.6)	99 (35.4)	
Service sector				
Private	524 (100)	344 (65.6)	180 (34.4)	.896
Public	446 (100)	291 (65.2)	155 (34.8)	
Dentists				
Women	595 (100)	379 (63.7)	216 (36.3)	.115
Men	370 (100)	254 (68.6)	116 (31.4)	
General practitioner	915 (100)	598 (65.4)	317 (34.6)	.772
Specialist	55 (100)	37 (67.3)	18 (32.7)	
Type of tooth				
Anterior	104 (100)	67 (64.4)	37 (35.6)	.913
Premolar	236 (100)	157 (66.5)	79 (33.5)	
Molar	630 (100)	411 (65.2)	219 (34.8)	
Patients' age (years)				
Mean (SD)	44.2 (14.2)	43.4 (14.2)	45.9 (14.0)	.009
Range, median	12–85, 43.8	12–85, 43.0	15–85, 44.9	
Dentists' age (years)				
Mean (SD)	45.4 (10.4)	46.0 (10.5)	44.2 (10.0)	.010
Range, median	24–75, 45.3	24–75, 45.9	24–75, 44.3	

SD, standard deviation.

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